DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 17, 2015

Visionsense LTD.
% Mr. Gerard J. Prud'homme
Hogan Lovells US LLP
555 13th Street, North West
Washington, District of Columbia 20004

Re: K150018
Trade/Device Name: VS3-IR-MMS System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: May 19, 2015
Received: May 19, 2015

Dear Mr. Prud'homme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150018

Device Name

VS3-IR-MMS System

Indications for Use *(Describe)*

The Endoscope Module of the VS3-IR-MMS System is intended for viewing internal surgical sites during general surgical procedures, for use in visualization of ventricles and structures within the brain during neurological surgical procedures, viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy, and shoulder and knee arthroscopic procedures. The Iridium Module of the VS3-IR-MMS System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Visionsense's VS3-IR-MMS System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Alex Chanin, CEO

Date Prepared: May 19, 2015

Name of Device and Name/Address of Sponsor

VS3-IR-MMS System

Common or Usual Name / Classification Name

Surgical Microscope / Angiographic X-ray System / Endoscopes and Accessories

Predicate Device

Novadaq Technologies SPY Imaging System (K063345)

Intended Use / Indications for Use

The Endoscope Module of the VS3-IR-MMS System is intended for viewing internal surgical sites during general surgical procedures, for use in visualization of ventricles and structures within the brain during neurological surgical procedures, viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy, and shoulder and knee arthroscopic procedures. The Iridium Module of the VS3-IR-MMS System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

Technological Characteristics / Principles of Operation

The VS3-IR-MMS System consists of the cleared base system and the Iridium Module that is the subject of this submission. The currently marketed VS3 system with endoscope functionality was cleared under the following product codes: GCJ (General Surgery Endoscope), GWG (Neurological Endoscope), and HRX (Orthopedic Arthroscope). The cleared base system consists of the following components and accessories: High Definition 3D Endoscope, High Definition 3D Camera with 3 control buttons and a focus adjustment knob, 2D Coupler, CCU, Light Source, and Display Monitor. The VS3-IR-MMS System that is the subject of this submission contains the previously cleared components of the cleared base system listed above, as well as a High Definition IR Fluorescence Scope (MMS), a Laser Light Source (LLS), associated software and VS_3 Iridium IR Fluorescence Kit. The new Iridium Module, which uses the newly added High Definition IR Fluorescence Scope (MMS)

and a Laser Light Source (LLS), as well as the cleared High Definition 3D Camera, Camera Control Unit (CCU), and Display Monitor, is used to generate florescence excitation illumination for external use in capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

In sum, the proposed VS3-IR-MMS System is built on the predicate base VS3 System that has already been cleared for the treatment of viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures, viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy, and shoulder and knee arthroscopic procedures (*see* K123467, K131434, K141002). The Iridium Module added to the cleared base system results in the following changes to the cleared system:

- Addition of a new scope ("MMS"), which is intended to provide a view of the surgical field from 20cm to 45cm above the patient.
- Addition of a Laser Light Source ("LLS") used to generate florescence excitation illumination.
- Software modifications to allow the new MMS with LLS to be used with the cleared system.
- Addition of the VS_3 Iridium IR Fluorescence Kit which contains the sterile ICG imaging agent used for fluorescence imaging.
- Additional indications for use with the new Iridium Module, which includes the MMS with LLS and associated software (described above) to include capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

The Iridium Module that is the subject of this submission is designed to work with the Indocyanine Green (ICG) IR fluorescence imaging agent supplied in the VS_3 Iridium IR Fluorescence Kit. Each VS_3 Iridium IR Fluorescence Kit contains the following:

- Six 25mg vials of sterile ICG imaging agent.
- Six 10ml vials of sterile Water for Injection.

ICG in blood has maximum excitation at 805nm and an emission band between 825nm and 850nm. VS_3 Iridium Module provides excitation light to the surgical field to excite the dye molecules and captures emission from the dye using an IR camera.

The VS3-IR-MMS System permits recording surgical procedures, storing them on removable storage devices, and playing the procedures back.

Performance Data

The subject device conforms to the following recognized standards:

Standards No.	Standards Organization	Standards Title
60601-1-2 (19-2)	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (Edition 3).
Standards No.	Standards Organization	Standards Title
60601-1 (19-4)	IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
Standards No.	Standards Organization	Standards Title
60601-1-4	IEC	Medical electrical equipment - Part 1: General requirements for safety, Collateral standard: Programmable electrical medical systems.
Standards No.	Standards Organization	Standards Title
60825-1 (12-273)	IEC	Safety of laser products - Part 1: Equipment classification, and requirements.

The system software was validated and performs as intended per the pre-specified requirements.

In addition, bench testing was conducted to verify that the subject device can detect and visualize anatomy and blood flow per the proposed indications for use of the Iridium Module. Specifically, 10mg of ICG was dilated in sterile water to a concentration equal to that of ICG in the blood of a representative human (*i.e.*, 2 ug/ml). Next, the ICG in sterile water diluted to representative human concentration was imaged directly to verify good quality imaging. Then, the sample of ICG in sterile water diluted to representative human concentration was covered with chicken skin and imaged to simulate visualization through skin.

On a related note, outside of the United States, a human hand was used in a simulated use testing environment to demonstrate that the Iridium Module has the capability to visualize blood flow corresponding to ICG dye fluorescence of blood vessels in the skin.

Lastly, an evaluation of the device was performed in free flaps in several human subjects outside the US and demonstrated that the device functions as intended with no adverse events reported using the system.

In all instances, the VS3-IR-MMS System using the Iridium Module functioned as intended and met all performance acceptance criteria.

Substantial Equivalence

The endoscope functionality of the base VS3-IR-MMS System was previously cleared. The proposed Iridium Module of the VS3-IR-MMS has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device (K063345). The minor technological differences between the VS3-IR-MMS System Iridium Module and its predicate device do not raise different questions of safety or effectiveness. Performance data demonstrate that the VS3-IR-MMS System Iridium Module is as safe and effective as the predicate device. Thus,

the VS3-IR-MMS Iridium Module is substantially equivalent. See the below comparison table of the Iridium Module of the updated VS3-IR-MMS and the Novadaq Spy Imaging device (K063345).

Attributes	**VS3-IR-MMS (proposed)**	**Spy (K063345)**
Manufacturer	Visionsense Ltd.	Novadaq Technologies Inc
Drape Usage	Yes	Yes
Imaging Agent	IR fluorescence dye (*e.g.*, Indocyanine Green-ICG)	IR fluorescence dye (*e.g.*, Indocyanine Green-ICG)
Imaging Head	Silicon Image Sensor	Silicon Image Sensor
Imaging Device	No direct or indirect patient contact	No direct or indirect patient contact
Light Source	Infrared Laser	Infrared Laser
Excitation Wavelength	805nm	805nm
Field of View	19cm x 14cm (40cm nominal distance)	19cm x 14cm (30cm nominal distance)
Imaging	Fluorescent Imaging	Fluorescent Imaging
Emission Band	825nm to 850nm	825nm to 850nm
Emission Capture	IR camera	IR camera

Conclusions

The VS3-IR-MMS System Iridium Module is substantially equivalent to the predicate device. Performance and clinical testing demonstrates that the newly added components to the proposed device performs substantially equivalent to the predicate device, and any differences in technological characteristics do not raise different questions of safety or efficacy compared to the predicate device.